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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,414	02/05/2004	Ben-Zion Dolitzky	1662/607061	6617

26646 7590 05/24/2005  
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EXAMINER

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ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/773,414

Applicant(s)

DOLITZKY ET AL.

Examiner

Anthony J. Paviglianiti

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

**Claims 1 – 46** are currently pending in the instant application and are subject to the following restriction.

**Election/Restrictions**

**Restriction to one of the following inventions is required under 35 U.S.C. 121:**

- I. Claims 1 – 11**, drawn to a process of making a compound of structure I, as depicted in **Claim 1**, using a carboxylic acid amide and a tetrazole derivative as starting materials, classified in Class 548, subclass 253.
- II. Claim 12 – 16 and 19 – 28**, drawn to a process of making a compound of structure I, using a valerimide derivative and first amine as starting materials, classified in Class 548, subclass 253.
- III. Claim 17**, drawn to a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole, as classified in Class 548, subclass 252.
- IV. Claim 18**, drawn to a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester, as classified in Class 560, subclass 122.
- V. Claims 29 – 34**, drawn to a process of making a compound of structure I, using a valeramide derivative and 2,6-lutidine and oxalyl chloride as starting materials, and an imidoyl chloride product as a synthetic intermediate, as classified in Class 548, subclass 253.

- VI. Claim 35**, drawn to a process of making irbesartan, using 1-(N'-pentanoylamino)cyclopentanecarboxylic acid amide and 5-(4'-bromomethyl-biphenyl-2-yl)-1-trityl-1H-tetrazole as starting materials, and the intermediate product 2-butyl-3-[[2'-(1-trityl-1H-tetrazol-5-yl)-biphenyl-4-yl] methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one, as classified in Class 548, subclass 253.
- VII. Claim 36**, drawn to a process of making irbesartan using a valerimidate derivative and a first amine as starting materials, and the synthetic intermediate product 2-butyl-3-[[2'-(1-trityl-1H-tetrazol-5-yl)-biphenyl-4-yl]methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one, as classified in Class 548, subclass 253.
- VIII. Claim 37**, drawn to a process of making irbesartan from a valeramide derivative and 2,6-lutidine and oxalyl chloride, as classified in Class 548, subclass 253.
- IX. Claim 38**, drawn to the compound 1-(1'-ethoxy) pentanaminylcyclopentanecarboxylate, as classified in Class 560, subclass 122.
- X. Claim 39**, drawn to the compound 4'-pentanaminy-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, as classified in Class 548, subclass 254.
- XI. Claims 40 – 41**, drawn to a process of making irbesartan, including steps using 4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl with a salt of ethyl valerimidate, and the synthetic intermediate compound 4'-[((1-ethoxy) pentanaminy) methyl]-2-(1H-tetrazol-5-yl) biphenyl, classified in Class 548, subclass 253.
- XII. Claims 42 – 44**, drawn to a process of making irbesartan, including a step using 4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl and ethyl 1-(1'-ethoxy)

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pentanaminy-cyclopentane carboxylate as starting materials, as classified in Class 548, subclass 253.

**XIII. Claims 45 – 46**, drawn to a process of making irbesartan, including a step using ethyl 1-amino-1-cyclopentanecarboxylate and a valerimide derivative as starting materials, as classified in class 548, subclass 253.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

**Rationale Establishing Patentable Distinctiveness Within Each Group**

**The above Groups represent general areas wherein the inventions are independent and distinct, each from the other, because of the following reasons:**

**Group I and Group II** are related as independent processes of making compounds of structure I, as depicted in **Claim 1**. Although the end-product of each synthesis is the same, the inventions of **Group I** and **Group II** use different starting materials, different reagents, and different reaction conditions, such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group II** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I and Group III** are related as a process for making compounds of structure I (as depicted in **Claim 1**) and a process of making the synthetic intermediate product N-valerimide

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5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group III** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group IV** are related as a process for making compounds of structure I and a process for making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group IV** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group V** are related as independent processes of making compounds of structure I, as depicted in **Claim 1**. Although the end-product of each synthesis is the same, the inventions of **Group I** and **Group V** use different starting materials, different reagents, and different reaction conditions, such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group V** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group VI** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in

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the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group VI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group VII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group VII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group VIII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group VIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group IX** are related as a process for making compounds of structure I and the compound 1-(1'-ethoxy) pentanaminylcyclopentanecarboxylate, respectively. The product of **Group IX** is not the same as the products made by the process of **Group I**, and a prior art

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reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group IX** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group X** are related as a process for making compounds of structure I and the compound 4'-pentanaminy-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, respectively. The product of **Group X** is not the same as the products made by the process of **Group I**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group X** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group XI** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group XII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I**



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and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group I** and **Group XIII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group I** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group III** are related as a process of making a compound of structure I and a process of making the synthetic intermediate product N-valerimidate 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group III** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group IV** are related as a process for making compounds of structure I and a process for making the synthetic intermediate product N-valerimidate-1-aminocyclopentane carboxylic acid ethyl ester, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one

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invention would not anticipate or render obvious the other invention. **Group II** and **Group IV** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group V** are related as independent processes of making compounds of structure I, as depicted in **Claim 1**. Although the end-product of each synthesis is the same, the inventions of **Group II** and **Group V** use different starting materials, different reagents, and different reaction conditions, such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group V** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group VI** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group VI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group VII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II**

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and **Group VII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group VIII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group VIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group IX** are related as a process for making compounds of structure I and the compound 1-(1'-ethoxy) pentanaminylcyclopentanecarboxylate, respectively. The product of **Group IX** is not the same as the products made by the process of **Group II**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group IX** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group X** are related as a process for making compounds of structure I and the compound 4'-pentanaminyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, respectively. The product of **Group X** is not the same as the products made by the process of **Group II**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group X** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group XI** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group XII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group II** and **Group XIII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group II** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

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**Group III** and **Group IV** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole and a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester, respectively. The processes of **Group III** and **Group IV** result in different synthetic products, and use different starting materials, different reagents, and different reaction conditions. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention; therefore, **Group III** and **Group IV** have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group III** and **Group V** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole and a process of making a compound of structure I, respectively. Because the processes in the two inventive Groups use different starting materials, different reagents, are conducted under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III** and **Group V** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group III** and **Group VI** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole and a process of making the chemical compound irbesartan, respectively. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III**

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and **Group VI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group III** and **Group VII** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole and a process of making the chemical compound, irbesartan, respectively. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III** and **Group VII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group III** and **Group VIII** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole and a process of making the chemical compound irbesartan, respectively. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III** and **Group VIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group III** and **Group IX** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole and the compound 1-(1'-ethoxy) pentanaminylcyclopentanecarboxylate, respectively. The compound of **Group IX** is not the same product as the product of the process of making the synthetic

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intermediate of **Group III**. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III** and **Group IX** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group III** and **Group X** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole and the compound 4'-pentanamyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, respectively. The compound of **Group X** is not the same product as the product of the process of making the synthetic intermediate of **Group III**. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III** and **Group X** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group III** and **Group XI** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole and a process of making the chemical compound irbesartan, respectively. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

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**Group III** and **Group XII** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-phenyl-1H-tetrazole and a process of making the chemical compound irbesartan, respectively. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group III** and **Group XIII** are related as a process of making the synthetic intermediate product N-valerimide 5'-(4'-aminomethylbiphenyl-2-yl)-1-phenyl-1H-tetrazole and a process of making the chemical compound irbesartan, respectively. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group III** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group V** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and a process of making a compound of structure I, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would



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not anticipate or render obvious the other invention. **Group IV** and **Group V** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group VI** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IV** and **Group VI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group VII** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IV** and **Group VII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group VIII** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction

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conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IV** and **Group VIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group IX** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and the compound 1-(1'-ethoxy) pentanaminylcyclopentane-carboxylate, respectively. The compound of **Group IX** is not the same product as the product of the process of making the synthetic intermediate of **Group IV**. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IV** and **Group IX** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group X** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and the compound 4'-pentanaminy-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, respectively. The compound of **Group X** is not the same product as the product of the process of making the synthetic intermediate of **Group IV**. Because the processes in the two inventive Groups use different starting materials, different reagents, are performed under different reaction conditions, and result in a different product, a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IV** and **Group X** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group XI** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IV** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group XII** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IV** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group IV** and **Group XIII** are related as a process of making the synthetic intermediate product N-valerimide-1-aminocyclopentane carboxylic acid ethyl ester and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IV** and **Group**

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**XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group V** and **Group VI** are related as a process of making a compound of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group V** and **Group VI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group V** and **Group VII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group V** and **Group VII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group V** and **Group VIII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Although the processes in the two inventive Groups use the same general types of starting materials (2,6 lutidine and oxalyl chloride), they use different reagents and reaction conditions, and result in a different product. A prior art reference which would anticipate one invention would not

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anticipate or render obvious the other invention. **Group V** and **Group VIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group V** and **Group IX** are related as a process for making compounds of structure I and the compound 1-(1'-ethoxy) pentanaminylcyclopentanecarboxylate, respectively. The product of **Group IX** is not the same as the products made by the process of **Group V**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group V** and **Group IX** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group V** and **Group X** are related as a process for making compounds of structure I and the compound 4'-pentanaminy-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, respectively. The product of **Group X** is not the same as the products made by the process of **Group V**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group V** and **Group X** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group V** and **Group XI** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group V** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group V** and **Group XII** are related as a process for making compounds of structure I and a process of making the chemical compound irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group V** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group V** and **Group XIII** are related as a process for making compounds of structure I and a process of making the chemical compound, irbesartan, respectively. Each of the processes in the two inventive Groups uses different starting materials, different reagents, and different reaction conditions, and results in a different product. A prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group V** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VI** and **Group VII** are related as two independent processes of making irbesartan from two different sets of starting materials (1-(N'-pentanoylamino) cyclo-pentanecarboxylic acid amide plus 5-(4'-bromomethyl-biphenyl-2-yl)-1-trityl-1H-tetrazole *versus* a valerimidate derivative and a "first amine"). Although the end-product and claimed synthetic intermediate of each process is the same, the inventions of **Group VI** and **Group VII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VI** and **Group VII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VI** and **Group VIII** are related as two independent processes of making irbesartan from two different sets of starting materials (1-(N'-pentanoylamino) cyclopentanecarboxylic acid amide plus 5-(4'-bromomethyl-biphenyl-2-yl)-1-trityl-1H-tetrazole *versus* a valerimidate derivative plus 2,6-lutidine plus oxalyl chloride). Although the end-product of each process is the same, the inventions of **Group VI** and **Group VIII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VI** and **Group VIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VI** and **Group IX** are related as a process of making the chemical compound irbesartan and the compound 1-(1'-ethoxy) pentanaminylcyclopentanecarboxylate, respectively. The product of **Group IX** is not the same as the product made by the process of **Group VI**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VI** and **Group IX** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VI** and **Group X** are related as a process for making the chemical compound irbesartan and the compound 4'-pentanaminy-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, respectively. The product of **Group X** is not the same as the product made by the process of **Group VI**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VI** and **Group X** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VI** and **Group XI** are related as two independent processes of making irbesartan using different materials (1-(N'-pentanoylamino) cyclopentanecarboxylic acid amide plus 5-(4'-

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bromomethyl-biphenyl-2-yl)-1-trityl-1H-tetrazole *versus* 4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl with a salt of ethyl valerimide). Although the end-product of each process is the same, the inventions of **Group VI** and **Group XI** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VI** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VI** and **Group XII** are related as two independent processes of making irbesartan using different materials (1-(N'-pentanoylamino) cyclo-pentanecarboxylic acid amide plus 5-(4'-bromomethyl-biphenyl-2-yl)-1-trityl-1H-tetrazole *versus* 4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl and ethyl 1-(1'-ethoxy) pentanaminyl-cyclopentane carboxylate). Although the ultimate product of each process is the same, the inventions of **Group VI** and **Group XII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VI** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VI** and **Group XIII** are related as two independent processes of making irbesartan using different materials (1-(N'-pentanoylamino) cyclo-pentanecarboxylic acid amide plus 5-(4'-bromomethyl-biphenyl-2-yl)-1-trityl-1H-tetrazole *versus* ethyl 1-amino-1-cyclopentanecarboxylate and a valerimide derivative). Although the ultimate product of each process is the same, the inventions of **Group VI** and **Group XIII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or



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render obvious the other invention. **Group VI** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VII** and **Group VIII** are related as two independent processes of making irbesartan using different starting materials and a different synthetic intermediate (a *valerimide* derivative plus a first amine, *via* the synthetic intermediate product 2-butyl-3-[[2'-(1-trityl-1H-tetrazol-5-yl)-biphenyl-4-yl]methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one (**Group VII**) *versus* a *valeramide* derivative and 2,6-lutidine and oxalyl chloride (**Group VIII**)) [emphasis added]. Although the ultimate products of both processes are the same, the inventions of **Group VII** and **Group VIII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VII** and **Group VIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VII** and **Group IX** are related as a process of making the chemical compound irbesartan and the compound 1-(1'-ethoxy) pentanaminylcyclopentane-carboxylate, respectively. The product of **Group IX** is not the same as the product made by the process of **Group VII**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VII** and **Group IX** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VII** and **Group X** are related as a process for making the chemical compound irbesartan and the compound 4'-pentanaminy-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, respectively. The product of **Group X** is not the same as the product made by the process of **Group VII**, and a prior art reference which would anticipate one invention would not anticipate

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or render obvious the other invention. **Group VII** and **Group X** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VII** and **Group XI** are related as two independent processes of making irbesartan using different materials and a different synthetic intermediate (a valerimide derivative plus a first “amine,” *via* the synthetic intermediate product 2-butyl-3-[[2'-(1-trityl-1H-tetrazol-5-yl)-biphenyl-4-yl]methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one (**Group VII**) *versus* 4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl with a salt of ethyl valerimide *via* the synthetic intermediate compound 4'-[[(1-ethoxy)pentanamyl]methyl]-2-(1H-tetrazol-5-yl) biphenyl (**Group XI**)). Although the ultimate products of both processes are the same, the inventions of **Group VII** and **Group XI** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VII** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VII** and **Group XII** are related as two independent processes of making irbesartan using different materials and a different synthetic intermediate (a valerimide derivative plus a “first amine,” *via* the synthetic intermediate product 2-butyl-3-[[2'-(1-trityl-1H-tetrazol-5-yl)-biphenyl-4-yl]methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one (**Group VII**) *versus* 4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl and ethyl 1-(1'-ethoxy) pentanamyl-cyclopentane carboxylate (**Group XII**)). Although the ultimate products of both processes are the same, the inventions of **Group VII** and **Group XII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious

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the other invention. **Group VII** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VII** and **Group XIII** are related as two independent processes of making irbesartan using different materials and a different synthetic intermediate (a valerimide derivative plus a “first amine,” *via* the synthetic intermediate product 2-butyl-3-[[2'-(1-trityl-1H-tetrazol-5-yl)-biphenyl-4-yl]methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one (**Group VII**) *versus* ethyl 1-amino-1-cyclopentanecarboxylate and a valerimide derivative (**Group XIII**)).

Although the ultimate products of both processes are the same, the inventions of **Group VII** and **Group XIII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VII** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VIII** and **Group IX** are related as a process of making the chemical compound irbesartan and the compound 1-(1'-ethoxy) pentanaminylcyclopentanecarboxylate, respectively. The product of **Group IX** is not the same as the product made by the process of **Group VIII**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VIII** and **Group IX** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VIII** and **Group X** are related as a process for making the chemical compound irbesartan and the compound 4'-pentanaminy-2-(1-trityl-1H-tetrazol-5-yl) biphenyl, respectively. The product of **Group X** is not the same as the product made by the process of **Group VIII**, and a prior art reference which would anticipate one invention would not anticipate

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or render obvious the other invention. **Group VIII** and **Group X** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group VIII** and **Group XI** are related as two independent processes of making irbesartan using different materials (a valeramide derivative and 2,6-lutidine and oxalyl chloride (**Group VIII**) *versus* 4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl with a salt of ethyl valerimidate *via* the synthetic intermediate compound 4'-[[(1-ethoxy)pentanaminy] methyl]-2-(1H-tetrazol-5-yl) biphenyl (**Group XI**)). Although the ultimate products of both processes are the same, the inventions of **Group VIII** and **Group XI** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VIII** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

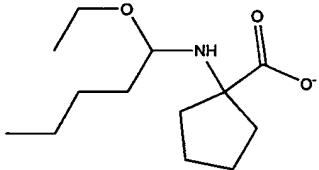
**Group VIII** and **Group XII** are related as two independent processes of making irbesartan using different materials (a valeramide derivative and 2,6-lutidine and oxalyl chloride (**Group VIII**) *versus* 4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl and ethyl 1-(1'-ethoxy) pentanaminy-cyclopentane carboxylate (**Group XII**)). Although the ultimate products of both processes are the same, the inventions of **Group VIII** and **Group XII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VIII** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

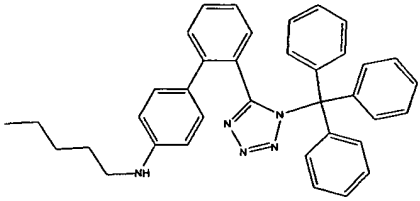
**Group VIII** and **Group XIII** are related as two independent processes of making irbesartan using different materials and a different synthetic intermediate (a valeramide derivative and 2,6-lutidine and oxalyl chloride (**Group VIII**) *versus* ethyl 1-amino-1-

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cyclopentanecarboxylate and a valerimidate derivative (**Group XIII**). Although the ultimate products of both processes are the same, the inventions of **Group VIII** and **Group XIII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group VIII** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

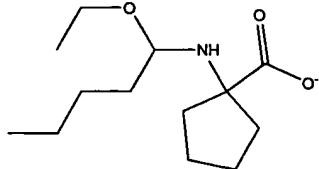
**Group IX** and **Group X** are related as the compound 1-(1'-ethoxy) pentanaminy-

cyclopentanecarboxylate, , and the compound 4'-pentanaminy-2-(1-

trityl-1H-tetrazol-5-yl) biphenyl, , respectively. The compounds

are separately classified in the art, and a prior art reference anticipating one of the compounds would not anticipate or render obvious the other, and thus **Group IX** and **Group X** represent separate and distinct inventions.

**Group IX** and **Group XI** are related as the compound 1-(1'-ethoxy) pentanaminy-

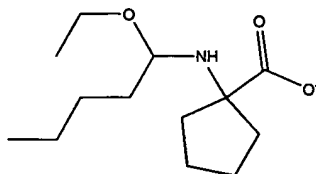
cyclopentanecarboxylate, , and a process of making irbesartan,

respectively. The product of **Group IX** is not the same as the product made by the process of **Group XI**, and a prior art reference which would anticipate one invention would not anticipate

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or render obvious the other invention. **Group IX** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

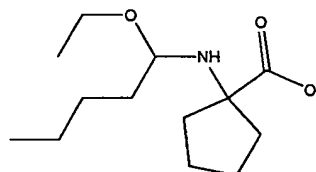
**Group IX** and **Group XII** are related as the compound 1-(1'-ethoxy) pentanaminyll-



cyclopentanecarboxylate, , and a process of making irbesartan,

respectively. The product of **Group IX** is not the same as the product made by the process of **Group XII**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IX** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

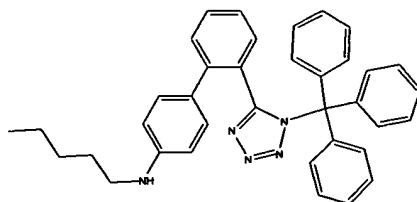
**Group IX** and **Group XIII** are related as the compound 1-(1'-ethoxy) pentanaminyll-



cyclopentanecarboxylate, , and a process of making irbesartan,

respectively. The product of **Group IX** is not the same as the product made by the process of **Group XIII**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group IX** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group X** and **Group XI** are related as the compound 4'-pentanaminyll-2-(1-trityl-1H-

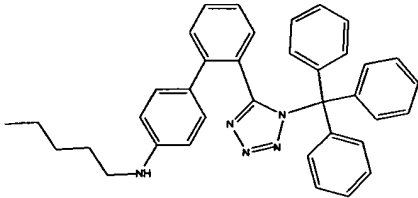


tetrazol-5-yl) biphenyl, , and a process of making irbesartan,

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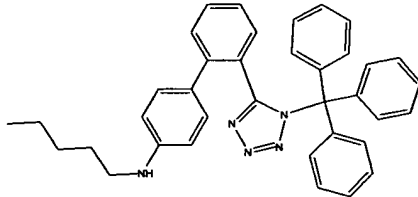
respectively. The product of **Group X** is not the same as the product made by the process of **Group XI**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group X** and **Group XI** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group X** and **Group XII** are related as the compound 4'-pentanaminy-2-(1-trityl-1H-

tetrazol-5-yl) biphenyl, , and a process of making irbesartan,

respectively. The product of **Group X** is not the same as the product made by the process of **Group XII**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group X** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group X** and **Group XIII** are related as the compound 4'-pentanaminy-2-(1-trityl-1H-

tetrazol-5-yl) biphenyl, , and a process of making irbesartan,

respectively. The product of **Group X** is not the same as the product made by the process of **Group XIII**, and a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group X** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group XI** and **Group XII** are related as two independent processes of making irbesartan from at least one different starting material (a salt of ethyl valerimidate (**Group XI**) *versus* ethyl

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1-(1'-ethoxy) pentanaminy-cyclopentane carboxylate (**Group XII**)). Although the ultimate products of both processes are the same, the inventions of **Group XI** and **Group XII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group XI** and **Group XII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group XI** and **Group XIII** are related as two independent processes of making irbesartan from different starting materials (4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl with a salt of ethyl valerimide (**Group XI**) *versus* ethyl 1-amino-1-cyclopentanecarboxylate and a valerimide derivative (**Group XIII**)). Although the ultimate products of both processes are the same, the inventions of **Group XI** and **Group XIII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group XI** and **Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

**Group XII** and **Group XIII** are related as two independent processes of making irbesartan from different starting materials (4'-aminomethyl-2-(1-trityl-1H-tetrazol-5-yl) biphenyl and ethyl 1-(1'-ethoxy) pentanaminy-cyclopentane carboxylate (**Group XII**) *versus* ethyl 1-amino-1-cyclopentanecarboxylate and a valerimide derivative (**Group XIII**)). Although the ultimate products of both processes are the same, the inventions of **Group XII** and **Group XIII** use different starting materials such that a prior art reference which would anticipate one invention would not anticipate or render obvious the other invention. **Group XII** and



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**Group XIII** therefore have different issues regarding patentability and enablement, and represent distinct subject matter.

In addition, because of the several separate and distinct inventions described above, as well as different classes and subclasses in the application, a search of the inventions in the application would require multiple divergent searches and impose a serious burden upon the examiner to perform a complete search of the defined areas. Therefore, for the reasons given above, the restriction set forth is proper, and not to restrict would impose a serious burden in the examination of this application.

**Advisory of Rejoinder**

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

**During a telephone conversation with Jack Starr, Esq., on March 9, 2005, the restriction requirements were discussed, but applicant did not elect by telephone.**

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed. 37 C.F.R. §1.143.

Applicant is further advised that a reply to this requirement must identify the specific compound that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

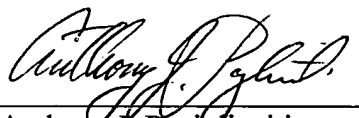
### **Conclusion**

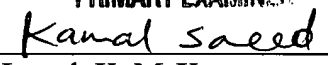
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, may be reached at (571) 272-0699. **The FAX phone number for the organization where this application or proceeding is assigned is (571) 273-8300.** Please note that this is a new central FAX number for all official correspondence.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
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TC-1600, Art Unit 1626

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Supervisory Patent Examiner  
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